Notice of Allowability	Application No.	Applicant(s)	
	10/696,635	DORSETT ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *October 29, 2003*.

2. ☒ The allowed claim(s) is/are *1-14*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 10-23-2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

1. Claims 1-14 are pending and allowed.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on October 23, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance: The claims in the present application are drawn to a kit comprising two vessels. The "first vessel containing rubella antigens comprising rubella E1 glycoprotein and rubella E2 glycoprotein and substantially free of rubella capsid protein; wherein the E1 and E2 glycoproteins are purified from rubella virus." This vessel is therefore read as comprising E1 and E2 glycoproteins purified from the virus (i.e. not recombinantly produced or derived from other sources that a whole rubella virus), and not comprising rubella capsid protein.

The second vessel is described as "containing an indicator reagent that specifically complexes with an anti-rubella IgM antibody." This limitation is read as requiring that the claimed indicator reagent is capable of distinguishing IgM antibodies that bind to the rubella E1 and E2 antibodies from other antibody types that may be found in the sample to be tested (e.g., will not recognize anti-rubella IgG antibodies).

In the parent application (U.S. 09/850,022, now U.S. Patent 6,670,117), the claims were drawn to a method of detecting anti-rubella IgM antibodies. The claims allowed in that prior application comprised the same language used in the presently considered kit claims. In the prosecution of that application, the method claims were rejected under 35 U.S.C. 103(a) as obvious over the teachings of Ghadessi et al., Clin. Chem., 42(6): S188, in view of van Sommeren et al., J. Virological Methods 63:37-46 and Zrein et al., U.S. Patent 5,427,792 (all of record in the October 2003 IDS). The teachings of these references were described as follows:

> Ghadessi teaches that anti-rubella IgM may be detected by a method involving the absorption of rubella antigens onto a surface. The reference also teaches that the antigen so absorbed may comprise the rubella E1 protein. The van Sommeren reference teaches that improved results in the detection of anti-rubella IgG in an immunoassay are achieved by using purified E1 and E2 rubella proteins as the antigens to which IgG binding is detected. From these two references, it would have been obvious to those in the art to use the antigen composition taught by van Sommeren in the immunoassay taught by Ghadessi.
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> Additionally, Zrein teaches the peptide epitopes of E1 and E2 rubella proteins, when used in anti-rubella antibody detection assays, improves the specificity of the assay. Column 8, lines 21-23. The reference further teaches that such an immunoassay may be conducted by adsorbing the peptides onto a solid substrate, such as was done in the Ghadessi reference. Column 10, lines 13-16. Finally, the reference teaches that such peptides may be used in the detection of either anti-rubella IgG, or anti-rubella IgM. Thus, the reference in effect teaches that the E1 and E2 proteins comprise epitopes that improve the specificity of each anti-rubella IgG and IgM antibodies. When the

considering the teachings of van Sommeren and Ghadessi in view of the teachings of Zrein, one skilled in the art would have had both a motivation to combine, and a reasonable expectation of success in the combination, of the van Sommeren reference with Ghadessi to achieve a method of detecting anti-rubella IgM with greater specificity. It would therefore have been obvious to those in the art to make a kit comprising the claimed components for use in such a kit.

In Response to this rejection, the Applicant submitted arguments relating the teachings of another reference, Seppänen et al. (J Clin Microbiol 29:1877-82- of record in the current application in the IDS filed on October 29, 2003). The Applicant argued that this reference constituted a teaching away from the claimed invention, In particular, the Applicant argued that the Seppänen reference tended to teach that use of recombinant E1 and E2 proteins in IgM assays "indicated that the reactivities of IgM antibodies were weak with the recombinant proteins." Thus, despite the teachings of the art that indicate that peptides derived from the proteins may be used to detect anti-rubella antibodies, the art as a whole does not appear to teach or suggest the use of purified rubella E1 and E2 proteins for the detection of anti-rubella IgM.

These teachings are in contrast to the teachings of the parent and present applications, in which the Applicant has shown that the use of this combination of antigens resulted in a method with a reduced incidence of false positives in the detection of anti-rubella IgM. See e.g., pages 17-19 of the present application. In view of the fact that the Seppänen reference appears to teach away from the use of the E1 and E2 proteins for the detection of anti-rubella IgM, and the teachings of the Applicant demonstrating

improved results when using the purified viral glycoproteins, the claims in the present application are found allowable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Zhang et al., J Clin Microbiol 30(4): 824-30. This reference teaches that anti-rubella IgM directed to the E1 and E2 proteins is detected in the acute phase of viral infection, whereas those of the C protein are present throughout the infective cycle. However, the reference does not teach or suggest that the use of isolated E1 and E2 proteins, in the absence of the C protein, would result in an improved specificity for anti-rubella IgM against the E1 and E2 proteins.
>
> Seppänen et al., J Clin Microbiol 29(9): 1877-82 (of record in the October 2003 IDS). This reference teaches the use of recombinant E1 and E2 proteins for the detection of anti-rubella IgM. Abstract, page 1878. However, the reference also indicates that the recombinant rubella antigens are different from those isolated from the virus due to differences in protein glycosylation. Page 1878 (section entitled "Purification of recombinant RV glycoproteins"). Because the structures of the disclosed recombinant and the claimed isolated antigens are different, the reference does not teach a kit comprising the E1 and E2 proteins isolated from the rubella virus and a reagent for the detection of IgM.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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